

Premarket Notification for Kaempferiae Rhizoma in VI-28

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NEW DIETARY INGREDIENT NAME: KAEMPFERIAE RHIZOMA (rhizomes of
Kaempferia galanga)

INTENDED USE: Kaempferiae Rhizoma is intended for use as a dietary ingredient in the dietary supplement product VI-28. The dietary supplement product will contain 30 mg of Kaempferiae Rhizoma per capsule, for a dietary intake of maximum 60 mg per day.

HISTORY OF USE/SAFETY EVIDENCE FOR NEW DIETARY INGREDIENT:

The history of use of Kaempferiae Rhizoma is established from a review of various Asian cultures. Kaempferia galanga (**Kaempferia galanga chekur, Vimala**) is cultivated in India, China, Malaysia, Indonesia, and Singapore. It is widely used as a flavoring in food, as well as a health aid. The rhizomes of Kaempferiae Rhizoma have been used to aid in abdominal pain, swelling, and rheumatism³¹.

Evidence of the safety of the dietary ingredient is shown in the study performed on the dietary supplement VI-28. A summary of the study and a copy are attached herewith³².

Evidence of safety for Kaempferiae Rhizoma is also shown in the scientific literature. In one study, the cytotoxicity effect of rhizomes of Kaempferia galangal against EBV genome carrying human lymphoblastoid cells (Raji) was performed. It was determined that Kaempferia galangal exhibited no cytotoxicity effect³³. In another study, the various constituents of Kaempferiae Rhizoma were determined³⁴. Safety information regarding many of the constituents can be found in the literature including cineol (which is major component of sage oil, an ingredient used in the U.S.³⁵), borneol³⁶, 3-carene (in which dairy farmers during

³¹ Othman et al. "Vasorelaxant Effects of Ethyl Cinnamate Isolated from Kaempferia galangal...", Planta Med. 68, pp. 655-657 (2002).

³² The letter from Dr. Laurence S.L. Shek and Anti-ageing Study show the results of administration of VI-28.

³³ Vimala et al. "Anti-tumor promoter activity in Malaysian ginger...", British Journal of Cancer 80, pp. 110-116 (1999).

³⁴ Kiuchi et al. "Studies on Crude Drugs effective on Visceral Larva..." Chemical and Pharmaceutical Bulletin, 36 (1) pp. 412-415 (1988). Constituents include cineol, borneol, 3-carene, camphene, kaempferol, kaempferide, cinnamaldehyde, p-methoxycinnamic acid, ethyl cinnamate, and ethyl p-methoxycinnamate.

³⁵ Farhat et al. "Seasonal changes in the composition of the essential oil...", (Abstract), PubMed record no. 11478969.

milking are regularly exposed to the compound³⁷), kaempferol (in which guinea pig enterocytes were exposed to the compound in concentration of 50-450 microM, and kaempferol was determined to be less toxic³⁸), and ethyl cinnamate (EC) (in which it was determined that EC, which is present in red wines as flavor, may be responsible for the vasorelaxant activity of the rhizome of *Kaempferia galanga*³⁹).

Based on the current use of *Kaempferia Rhizoma* in cooking in many Asian cultures, studies conducted on the toxicity of the ingredient, scientific articles disclosing and researching many of the constituents of the ingredient, and the study performed on VI-28, it is believed that *Kaempferia Rhizoma* as used in the VI-28 dietary supplement can reasonably be expected to be safe.

³⁶ Id.

³⁷ Sunesson et al. "Airborne chemical compounds...", (Abstract), PubMed record no. 11354733.

³⁸ Canada et al. "The toxicity of flavonoids..." (Abstract), PubMed record no. 2734797.

³⁹ Id. at 26.